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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,817	10/03/2003	Paul J. Bobrowski	PHMC0745-023	3270

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1655

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/678,817

Applicant(s)

BOBROWSKI, PAUL J.

Examiner

Christopher R. Tate

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1003</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 1-19 are presented for examination on the merits.

#### ***Claim Objections***

Claims 1 and 17 are objected for the following reasons:

In claim 1, the phrase "in a mammals ... and botanical component selected from the group consisting of; an extract of from the plant material of the *Croton* species and an aextract of the plant material from the *Uncaria* species" (lines 1-5) is grammatically and typographically incorrect (as well as somewhat confusing). Accordingly, it is suggested that this phrase be amended to recite -- in a mammal ... and a botanical component selected from the group consisting of an extract obtained from plant material of a *Croton* species and an extract obtained from plant material of an *Uncaria* species-- or similar phraseology.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 17 recites the limitation "of botanical materials and nutrients" in line 2. There is insufficient antecedent basis for these limitations in the claim (i.e., claim 1, from which claim 17 depends, does not recite "botanical materials" or "nutrients" therein. In addition, the overall phrase "effective dose comprises of botanical materials and nutrients which reduces" (line 2) is unclear and confusing - e.g., is this attempting to define the botanical component of claim 1 as well as the dose further comprising nutrients, or something else?

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted state of the art, Illek et al. (IDS Ref. - 12/2000), Miller et al. (IDS Ref - Am. J. Physiol. Gastrointest. Liver Physiol., 2000), and Inomata (US 2001/0012524).

A method of treating the symptoms of diarrhea in a mammal via administering an effective dose of a potassium salt, a sodium salt, a bicarbonate, a sugar, and a botanical component selected from a plant extract obtained from a *Croton* species or an *Uncaria* species is claimed.

As readily admitted by Applicant, the administration of an oral rehydration solution (ORS) that contains effective amounts of glucose, sodium bicarbonate, potassium (in the form of a salt) and sodium (in the form of a salt) is well known in the prior art to be the gold standard for the treatment of diarrhea and that the instant invention relates to a combination of the prior art anti-diarrheal ORS plus the botanical component(s) instantly claimed. Further, as readily admitted by Applicant, latex sap (which would intrinsically contain less than 10% water) extracted from the bark of *Croton* species, as well as decoctions (which read upon extracts) from the bark of *Uncaria* species, have both been used in the prior art to treat gastrointestinal distress and, further, that the latex extracted from various *Croton* species (aka *Sangre de grado*) is well known in the prior art to be an effective agent in managing diarrhea (see, e.g., page 1, paragraph [003] - page 4, paragraph [010] of the instant specification).

Illek et al. and Miller et al. also each beneficially teach the use of latex from *Croton* species, as well as extracts thereof (such as SP-303 and/or SB-300), for treating diarrhea (see entire documents).

Inomato beneficially discloses that an extract of *Uncaria* has long been known as an effective medicine for treating diarrhea (see, e.g., page 1, paragraph [0011]).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat diarrhea in a mammal by administering result-effective amounts of ORS in combination with an extract from either of the claimed plant species based upon the admitted state of the art and the beneficial teachings provided by the cited references, as discussed above, with respect to the well known anti-diarrheal activity such ingredients were known to possess. Accordingly, it would have been obvious to combine the instantly claimed

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ingredients (e.g., ORS plus one or both of the claimed botanical extract ingredients) for their known benefit since each is well known in the art for the same purpose (i.e., treating diarrhea) - the idea for combining them flows logically from their having been used individually in the prior art, and to use the combination for that purpose - such as within the instantly claimed method. Please note that the recited functional properties instantly claimed would be intrinsic to the cited prior art *Croton* and *Uncaria* extracts discussed above. Further, such anti-diarrheal extract preparations would also intrinsically read upon a dietary supplement, a food, a food additive, and/or one or more of the other pharmaceutical forms instantly claimed. The adjustment of particular conventional working conditions (e.g., determining result-effective amounts of such ingredients; adding a conventional agent such as a coloring, flavoring, or sweetening agent such as sucrose therein, and/or providing such an anti-diarrhea preparation within one of various commonly-employed pharmaceutical forms) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the admitted state of the art (as instantly disclosed) and the cited references - as discussed above, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate  
Primary Examiner  
Art Unit 1654